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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/075,097 | 02/13/2002 | Nnochiri N. Ekwuribe | 9233-46 | 7253 |

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EXAMINER

KOSAR, ANDREW D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/075,097 | Applicant(s) EKWURIBE ET AL. | |
| | Examiner Andrew D. Kosar | Art Unit 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 114-169 and 208-213 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 114-169 and 208-213 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/31/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 114-169 and 208-213 are pending and have been examined on the merits.

Response to Arguments

Applicant's amendments to the specification and claims are acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections of claims 142-169 and 208-213 under 35 USC 112, second paragraph, are herein withdrawn, in view of Applicant's amendments to the claims.

Applicant's arguments filed January 10, 2005 have been fully considered but they are not persuasive.

Claims 114-122, 126, 127, 129-150, 154, 155, 157-169, and 208-213 stand rejected under 35 USC 102(a) as anticipated by Allaudeen, et al. Claims 114-122, 126, 127, 129-150, 154, 155, 157-169, and 208-213 stand rejected under 35 USC 102(b) as anticipated by Radha Krishnan, et al. Claims 114-127, 129-169, and 208-213 stand rejected under 35 USC 103(a) as unpatentable over Allaudeen or Radha Krishnan. Claims 114-169 and 208-213 stand rejected under 35 USC 103(a) as unpatentable over Allaudeen or Radha Krishnan in view of Vajo.

Applicant asserts that the *prima facie* case of obviousness by the Examiner is deficient in that the Examiner has "misunderstood" Applicant's use of monodispersed "as used in the present invention." Applicant further asserts that "A coded reference to a drug without a description of the structure of that drug does not enable one of skill in the art to make the drug."

With regards to the first argument, 'monodispersed' can relate to size, shape, or as the Examiner concluded, purity. This is not repugnant to the art, and Applicant has not provided a

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definition in the specification to support Applicant's assertion. Thus, the argument is not persuasive.

With regards to the second argument, Applicant asserts that "In the pharmaceutical industry, companies often seek to balance the need for peer reviewed scientific publications with the need to prohibit disclosures that would result in a loss of patent rights" by publication of 'coded references'. Applicant asserts that the prior art discloses only a 'coded reference' and one of skill in the art would not be put in possession of the instant invention. Applicant is directed to Radhakrishnan (#14, PTO-1449 1/23/04) which clearly identifies HIM2 structurally and by 'code name', e.g.- Figure 1. Furthermore, Applicant's arguments fail to dispute that the compound disclosed in the prior art is, in fact, the instantly claimed compound as set forth by the Examiner, but merely assert that the coded reference does not lead to the compound. Because the compound and the 'coded reference' were indeed known together in the art, Applicant's arguments are not persuasive.

For these, and the reasons of record, the rejections of claims 114-122, 126, 127, 129-150, 154, 155, 157-169, and 208-213 under 35 USC 102(a) as anticipated by Allaudeen, et al., claims 114-122, 126, 127, 129-150, 154, 155, 157-169, and 208-213 under 35 USC 102(b) as anticipated by Radha Krishnan, et al., claims 114-127, 129-169, and 208-213 under 35 USC 103(a) as unpatentable over Allaudeen or Radha Krishnan, and claims 114-169 and 208-213 under 35 USC 103(a) as unpatentable over Allaudeen or Radha Krishnan in view of Vajo are maintained.

NO CLAIMS ARE ALLOWED.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913.

The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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